

REMARKS

Claims 23-38 currently appear in this application. The Office Action of April 8, 2005, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. The Examiner alleges that the specification as filed fails to provide written description support for the new term "specific hemolysin-producing fungus."

Attention is directed to paragraph 0046 on page 13 of the specification as filed:

An antibody which specifically binds an antigenic portion of the protein is also provided for each fungal hemolytic protein. The term "specifically bind[s]" means an antibody specifically binding a protein which does not substantially cross react with any antigen other than the hemolysin fungal protein, such that the intended antigen can be detected."

It is clear from this paragraph, as well as a reading of the specification as a whole, that the present invention is directed to detecting specific antibodies. This can only be accomplished by using a hemolysin specific to the fungus sought to be detected.

Rejections under 35 U.S.C. 112

Claims 23-29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

This rejection is respectfully traversed. Paragraph 0046 specifically states that the antibodies specifically bind protein which does not substantially cross react with any antigen other than the hemolysin fungal protein. It is clear to one skilled in the art that this means the hemolysin is species-specific, as paragraph 0046 states that an antibody which specifically bind an antigenic portion of the protein is also provided for each fungal hemolytic protein. It is respectfully submitted that one skilled in the art would appreciate that this means that each fungal hemolytic protein is specific for each fungus.

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

This rejection is respectfully traversed. Paragraph 0036, beginning on page 9, specifically states that it can be determined if a building holds fungi that produce hemolysin. A strain of a fungus obtained from the building is grown in a synthetic medium. The culture filtrate is applied to a plate. If the filtrate is hemolytic, the strain is problematic and may pose a health threat. This certainly teaches one how to obtain a hemolysin from a building sample. In an embodiment of the invention, hemolysin can be recovered from the sample if hemolysin-producing fungi are in the sample, and immunologically detecting the fungal hemolysin.

Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed. First of all, one does not know if the sample contains hemolysin, which is why the claim recites "if hemolysin-producing fungi are present in the sample." The method is directed to determining if a building contains a hemolysin-producing fungus. If there is no hemolysin-producing fungus present in the building, one cannot obtain hemolysin from the sample and therefore no complex will be formed with the labeled antibodies.

Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

This rejection is respectfully traversed. As discussed *supra*, there is basis in the specification for the recitation that the hemolysin is species-specific. The fact that antibodies cannot cross-react with other than the specific hemolysin from a specific fungus means that the hemolysin is species-specific.

As the Examiner is well aware, there is no requirement that the specification recite the claimed invention *in haec verba*. New claims must be supported in the specification through express, implicitly, or inherent disclosure. It is respectfully submitted that one skilled in the art, reading the present specification, would readily recognize that the hemolysin is species-specific, or the method for detecting a specific fungus would not be operational.

Art Rejections

Claims 23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakaguchi et al. in view of Harlow et al.

This rejection is respectfully traversed. Applicant has demonstrated that the detection method of the present

invention has worked with *S. chartarum*, beginning at paragraph 0025 on page 6. Antibodies to the *S. chartarum* were produced and were used to detect the fungal hemolysin.

Contrary to the Examiner's assertion, paragraph 0046 of the specification the term "specifically bind" means an antibody specifically binding a protein which does not specifically cross react with any antigen other than the hemolysin fungal protein, such that the intended antigen can be detected.

There is nothing in Sakaguchi et al. that would lead one skilled in the art to recognize that many fungi produce hemolysins, and each hemolysin is specific to that fungus. Harlowe adds nothing, as it merely instructs one skilled in the art to make antibodies, and is silent with respect to specificity of the antibodies.

The claims have been amended to recite that the antibodies only bind to the hemolysin produced by a specific fungus. Support for this amendment can be found in the specification as filed at paragraph 0046. There is nothing in any of the art cited that even suggests that one can detect fungi based upon hemolysin specific to each fungus.

Specific fungal hemolysins can be isolated and used to produce antibodies for testing an animal's exposure to a fungus. There is no need to recite a structural definition in

the claims of the fungal hemolysins, as it is clear from the specification that each fungus that produces hemolysin produces a hemolysin specific for that fungus. While immunoassays have been known in the art for more than 30 years, there has been no reliable test for immunologically detecting the presence of fungi, because normal antibody production to the body or mycelium of many fungi does not occur in humans (specification, paragraph 0007). One skilled in the art can readily produce antibodies to hemolysins, which antibodies can then be used to detect the presence of hemolysins in animals.

The claims, particularly beginning with claim 23, specifically recite "A method for determining if an animal has been exposed to a specific hemolysin-producing fungus..."

Claim 33 is rejected under 35 U.S.W.C. 102(b) as being anticipated by Sakaguchi et al.

This rejection is respectfully traversed. Sakaguchi et al. did not recognize that specific fungi produce specific hemolysins. Sakaguchi et al. merely exposed a rat to a fungus and detected the extent of invasion of the fungus. For this, Sakaguchi et al. obtained tissue samples to detect which organs the fungus had invaded. This is not at all the same as determining if an animal has been exposed to a specific

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fungus, as Sakaguchi et al. were merely measuring degree of infection.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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